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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/620,669

07/16/2003

Kathleen M. Hanley

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06/08/2006

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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,669

Applicant(s)

HANLEY ET AL.

Examiner

David H. Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group I, claims 1-26 and 28-34 in the response filed on 6 April 2006 is acknowledged. Applicant's statement concerning cancellation of claims 27 and 35-37 in said response is noted, but Applicant has not filed any amendment to the claims under 37 CFR § 1.121(c) of record. Claims 1-37 are still pending in the instant application. Upon further consideration, the Examiner has rerestricted the claims as outlined below. The Examiner apologizes for any inconvenience to the Applicant.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
- I. Claims 1-26 and 28-34, drawn to a method of reducing the amount of protein of interest cleaved by a hydrolase activity in a host cell and a host cell produced therefrom wherein the genetic element capable of reducing a hydrolysis activity in a host cell is a sense encoding element, classified in class 800, subclass 278, for example.
 - II. Claims 1-20, 25, 26 and 28-34, drawn to a method of reducing the amount of protein of interest cleaved by a hydrolase activity in a host cell and a host cell produced therefrom wherein the genetic element capable of reducing a hydrolysis activity in a host cell encodes an antisense element, classified in class 800, subclass 286, for example.
 - III. Claims 1, 2, 11-20, 26 and 28-34, drawn to a method of reducing the amount of protein of interest cleaved by a hydrolase activity in a host cell and a host cell produced therefrom wherein the genetic element capable

of reducing a hydrolysis activity in a host cell is a ribozyme, classified in class 800, subclass 285, for example.

- IV. Claims 1, 2, 11-20, 26 and 28-34, drawn to a method of reducing the amount of protein of interest cleaved by a hydrolase activity in a host cell and a host cell produced therefrom wherein the genetic element capable of reducing a hydrolysis activity in a host cell induces expression of a protease inhibitor, classified in class 800, subclass 278, for example.
- V. Claim 27, drawn to a polynucleotide comprising a substantially similar or complementary sequence of a coding sequence of a Nicotianalysin protease, classified in class 536, subclass 23.2, for example.
- VI. Claims 35 and 36, drawn to a composition of purified Nicotianalysin, classified in class 530, subclass 370, for example.
- VII. Claim 37, drawn to a method of cleaving a polypeptide using a Nicotianalysin, classified in class 435, subclass 23, for example.

Claims 1-20, 25, 26 and 28-34 are generic to Groups I and II, and claims 1, 2, 11-20, 26 and 28-34 are generic to Groups I-IV. Generic claims will be examined to the extent they read upon the elected invention.

The inventions are distinct, each from the other because of the following reasons:

- 3. Inventions I-IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of

Art Unit: 1638

operation, function, or effect. See MPEP § 806.05(j). In the instant case, the different processes use different starting materials, and the genetic element capable of reducing a hydrolysis activity in a host cell for each group has a different function within the host cell.

4. Inventions I, II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polynucleotide of Group V can be used in a materially different process than that of Group I or II, such as in a DNA isolation method. In addition, the process of Group I or II can be practiced using a materially different product than that of Group II, such as a ribozyme as exemplified by claim 2 of Group III.

5. Inventions I-IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are unrelated because the product of Group VI cannot be made using the process of Group I, II, III or IV, which requires inhibition of expression.

6. Inventions I-IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are unrelated because the process of Group I, II, III or IV has

different starting materials, different method steps and different end products than the process of Group IV.

7. Inventions III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are unrelated because the product of Group V cannot be use in the method of either Group III or IV.

8. Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the composition of Group VI can be used in a materially different process than that of Group VII, such as in producing antibodies.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and because the search required for one of the groups is not required for another, restriction for examination purposes as indicated is proper.

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise

Art Unit: 1638

include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR § 1.116; amendments submitted after allowance are governed by 37 CFR § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Applicant is advised that the reply to this requirement to be complete within one month (not less than 30 days) must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

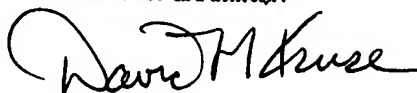
Art Unit: 1638

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.
1 June 2006

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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